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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,531	12/14/2001	Sukhendu B. Dev	GENE1180-2	1163

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EXAMINER

LAM, ANN-Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/24/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/020,531

Applicant(s)

DEV ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9, 17-20, 23-26 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 16 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 17-20, 23-26 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 7-13, 16, 17-20, 23-26 and 29-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: (Group I) the embodiment in claim 1 and its dependent claims and claim 17 and its dependent claims; (Group II) the embodiment in claim 10 and its dependent claims; (Group III) the embodiment in claim 36; and (Group IV) the embodiment in claim 37.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Daniel Chambers on February 20, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4, 7-9 and 17-20, 23-26 and 29-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-13, 16 and 35-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9 and 17-20 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al., 5,505,700.

As to claim 1, Leone et al. discloses a catheter (11) having at least one inflatable balloon portion (16 and 17); at least one infusion opening (19) for introducing the

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composition into a vessel; a first electrode (35) on the catheter positioned adjacent to at least one infusion opening ; and a second electrode (36) on the catheter positioned such that the infusion opening is disposed between the first electrode and the second electrode, wherein the second electrode is spaced a distance that allows an electric field to be generated when a voltage is applied between the first and second electrodes after the catheter has been inserted into the vessel, wherein the electric field is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

With respect to claims 2, 11, 18, an electrical source is connected to the first and second electrodes for applying a voltage between the electrodes, see column 4, line 61.

With respect to Claims 3, 12 and 19, the vessel is a blood vessel (22).

As to claims 4, 13 and 20, the first electrode (35) is formed at least in part by a biologically inert material, see column 4, lines 56-57.

As to claim 14, the second electrode is a guidewire in the catheter, see column 4, line 63.

As to claim 7, the catheter has two inflatable balloon portions (16 and 17).

As to claim 8, the at least one infusion opening (19) is between the two inflatable balloon portions (16 and 17), see Figure 2.

As to claim 9, the first electrode (35) is coincident with the at least one infusion opening (19).

As to claim 17, Leone et al. discloses at least one inflatable balloon portion (17) at a position other than the distal end of the catheter; proximal to the at least one

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inflatable balloon portion, an infusion opening (19) for introducing a composition; a first electrode (35) positioned adjacent to or integral with the infusion opening; and a second electrode (36, near balloon 16) on the catheter positioned proximal to but spaced from the first electrode a distance that allows an electric field to be generated when a voltage is applied between the first and second electrodes after the catheter has been inserted into the vessel, wherein both the first and second electrodes are located proximal to the at least one balloon portion and the electric field is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

As to claim 18, an electrical source (15) is connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

As to claim 23 and 25, the first and second electrode is separately selected to be a single electrode or multiple electrodes, see column 4, lines 57-59.

As to claims 24, and 26, the multiple electrodes are interdigitated electrodes or concentric ring electrodes, see column 4, lines 63-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700.

Leone et al. teach the invention substantially as claimed, see above. However, Leone et al. does not specifically disclose that the first and second electrodes are suitable to receive an electric pulse having an electroporating voltage in the range as claimed, or wherein the electric field strength is in the range as claimed.

Leone et al. however does teach that the invention can be used for iontophoresis or electroporation, see column 7, lines 39-44, and thus it would have been obvious to vary the Leone et al. device such that the device is capable of receiving an electric pulse having an electroporating voltage or electric field strength as specifically claimed, as necessary for achieving iontophoresis or electroporation. Also, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

02/23/04